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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/726,962 | 12/03/2003 | David Ernest Hartley | PA-5356-RFB | 4369 |

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COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

| EXAMINER | |
|---|---|
| DOWE, KATHERINE MARIE | |
| ART UNIT | PAPER NUMBER |
| 3734 | |
| MAIL DATE | DELIVERY MODE |
| 09/03/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/726,962 | HARTLEY ET AL. | |
| | Examiner | Art Unit | |
| | KATHERINE M. DOWE | 3734 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *28-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. The following is a complete response to the amendment filed 5/29/2008.

2. Claims 28-34 are currently pending.

### *Claim Rejections - 35 USC § 112*

3. The amendments to claims 28 and 34 are acknowledged. Accordingly, the rejection of the claims under 35 U.S.C. 112, second paragraph, as set forth in the 4/2/2008 Office Action is withdrawn.

### *Claim Rejections - 35 USC § 103*

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andreas et al. (US 7,147,656) in view of Hartley et al. (US 6,939,370). Regarding claims 28 and 31-33, Andreas et al. disclose the device substantially as claimed including a tubular prosthesis (30) with the distal end including at least one self expanding stent (col 2, ln 27-39). The prosthesis is everted with the proximal and distal ends extending towards the distal end of the deployment device, the central portion extending proximally, and the proximal end within the distal end (Fig 2A). The proximal end of the prosthesis is capable of being surgically fastened adjacent and around the aortic heart valve and the distal end is capable of extending into the descending aorta. The deployment device comprises a central catheter (36) with a nose cone, or distal end; a deployment catheter (34) coaxially around the central catheter; and a manipulator (32) coaxially

around the deployment catheter. The device comprises means to lock the movement of the deployment catheter with respect to the central catheter, as seen in Figs 2A-2B when the deployment catheter and central catheter are advanced forward together with respect to the manipulator (col 5, ln 8-10). The central portion of the prosthesis is releasably mounted to the manipulator, the proximal end of the prosthesis is fastened to the distal end of the deployment catheter, and the distal end of the prosthesis is fastened to the nose cone dilator (Figs 2A-2C).

However, Andreas et al. do not disclose the nose cone includes means to retain the distal end of the prosthesis with the assistance of a trigger wire. Hartley et al. disclose a similar deployment device and prosthesis combination (Fig 2). Hartley et al. teach the deployment device comprises a trigger wire arrangement to maintain the prosthesis in the retracted position during advancement to the deployment site (col 4, ln 12-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Andreas et al. to include a trigger wire to more securely hold the prosthesis in place about the deployment device in a retracted position during advancement to the desired site within the patient's vasculature.

Regarding claim 29, Andreas et al. do not disclose a portion of the prosthesis, or self expanding stent, is covered. Hartley et al. disclose a similar prosthesis (col 5, ln 47-53) with one portion comprising a covered self expanding stent (27) and another portion comprising an uncovered self expanding stent (29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Andreas et al. to include a cover for a distal portion of the prosthesis, thereby enhancing the interface between the prosthesis and the inner vessel wall.

Regarding claim 30, Andreas et al. do not disclose the uncovered self expanding stent of the prosthesis comprises barbs. Hartley et al. teach the uncovered portion of the prosthesis may include barbs (col 6, ln 1-2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Andreas et al. to include barbs to securely position the prosthesis in place and prevent undesired migration of the prosthesis after implantation.

Regarding claim 34, Andreas et al. disclose a central catheter (36) and the distal end of the central catheter may be interpreted to be a nose cone. However, Andreas et al. do not disclose the nose cone is in the form of a proximally opening capsule. Hartley et al. teach a central catheter with a nose cone (3) that has a proximally opening capsule. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nose cone of Andreas et al. to include a proximally opening capsule such that the stenosed area may be more easily traversed during the delivery state in which the prosthesis is in the contracted condition retained against the nose cone.

***Response to Arguments***

6. Applicant's arguments filed 5/29/2008 have been fully considered but they are not persuasive. Applicant argues Andreas does not teach prosthesis is releasably mounted to the deployment device in three places: (1) the central portion releasably mounted to the manipulator, (2) the proximal end fastened to the distal end of the deployment catheter, and (3) the distal end of the prosthesis fastened to the nose cone dilator. The Examiner respectfully traverses the Applicant's remarks. As the Applicant acknowledges, the prosthesis is held in the delivery

device. Thus, the prosthesis is releasably fastened, or releasably fixed/held in place relative to the deployment device at the at least three locations listed above. The Examiner notes claim 28 does not recite a particular fastening method and thus the term is given its broadest reasonable interpretation.

7. Furthermore, Applicant argues the outer tube, or manipulator, is not movable with respect to the other tubes; it remains stationary while the other tubes move. The Examiner notes that since the other tubes may move while the manipulator remains stationary, then relative movement between the manipulator and other tubes is indeed present.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Katherine Dowe
August 27, 2008

/K. M. D./
Examiner, Art Unit 3734